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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/931,721	09/16/97	PAPADOPOULOU	B 1038-729MIS:
			EXAMINER
			HAYES, R
		ART UNIT	PAPER NUMBER
		1645	

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AIR MAIL

DATE MAILED: 08/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
08/831,721

Applicant(s)

Papadopoulou et al

Examiner  
Robert C. Hayes

Group Art Unit  
1645



☒ Responsive to communication(s) filed on May 21, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 3-7, 9, 10, and 21 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 3-7, 9, 10, and 21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 05/21/99 has been entered.
2. The rejection of claims 1-6 & 11-16 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to either the cancellation or amendment of the claims, and the structural definition of GM-CSF on pages 3 & 14, and Figure 3 of the specification.
3. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, for lack of proper antecedent basis is withdrawn due to the cancellation of this claim.
4. The provisional rejection of claims 1-16 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16 of copending Application No. 08/713768 is withdrawn due to the cancellation of the appropriate claims in each application, as indicated on page 6 of the response.
5. The rejection of claims 1-6 & 10 under 35 U.S.C. 101 for being directed to nonstatutory subject matter is withdrawn either due to the cancellation or amendment of the claims.
6. The rejection of claims 1-3 & 10 under 35 U.S.C. 102(b) as being anticipated by Moore et al. is withdrawn either due to the cancellation or amendment of the claims.

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7. Applicants' arguments filed 05/21/99 as paper # 8 have been fully considered but they are not deemed to be persuasive.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Amended claims 1, 3-4, 5-6, 10 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al., in view of Wong et al., for the reasons made of record for original claims 1-3 & 10, and as follows.

Applicants argue on page 3-5 of the response that Moore et al. teach only GM-CSF cytokine expression "by the BMMs", in which "we were unable to detect GM-CSF protein in supernatants from infected cells". The Examiner agrees.

However, the amendment of the claims now require transfection with a plasmid containing GM-CSF, in which Applicants' correctly point out sufficient motivation for one of ordinary skill in the art at the time of Applicants' invention to transform Moore's *Leishmania donavani* "macrophage infecting parasite" (i.e., as it relates to new claims 1, 3 & 21), which intrinsically also expresses the cytokines Il-6, TNF- $\alpha$  and TGF- $\beta$  (pg. 2935; as it relates to claim 10), with the human and murine constructs of Wong et al. (Figs. 2 & 3; as it relates to claims 5-6), in order to increase GM-CSF protein levels to detectable levels. Additional motivation resides in that such transformation of *Leishmania donavani* with a GM-CSF expressing plasmid would more

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efficiently prevent apoptosis of BMMs which, therefore, increase BMM survivability and viability (pg. 2935, last two *pp*, and last *pp* of pg. 2935); and thereby, decrease overall *Leishmania* infectivity and survivability (i.e., as it relates to claim 4).

10. Amended claims 1, 3-6, 7-8, 10 & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al., in view of Wong et al., and further in view of Laban et al., for the reasons made of record and as indicated above in *pp* #9.

11. Claim 9 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al., in view of Maltashewski et al., for the reasons made of record and as indicated above in *pp* #9.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
July 29, 1999